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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,881	06/26/2001	John J. Voorhees	1718-010A	9061

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/891,881	VOORHEES ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0702*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 8-16 in its response to the restriction requirement is acknowledged. The traversal is based on the grounds that the cited reference is directed merely to novel compounds that can inhibit EGF-R, and not to a combination of an EGF-R inhibitor with P-450 inhibitor and/or a dermatologically suitable carrier. Furthermore, the Groups have not acquired a separate status in the art.

Applicant's arguments are not found persuasive because, as Examiner explained in the previous restriction requirement of 01/30/2004, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05 (h)). In the instant case, the EGF-R protein tyrosine kinase inhibitor of Group II can be used in a materially different process of tumor therapy (i.e. US 20030203901 A1). Therefore, Groups I and II are independent and distinct, each from the other. They have acquired a separate status in the art as separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each

case. Thus, it would be an undue burden to examine all the above inventions in one application.

The restriction requirement is still deemed proper and is therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a composition to inhibit UV-inducement of MMPs in human skin due to exposure of the skin to UV radiation, the specification does not enable any person skilled in the art to prepare a composition for preventing induction of MMPs in human skin due to exposure of the skin to UV radiation.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition for preventing induction of MMPs in human skin due to exposure of the skin to UV radiation. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard

for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 7-16 of the specification, a composition to inhibit UV-inducement of MMPs in human skin due to exposure of the skin to UV radiation. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a composition for preventing induction of MMPs in human skin due to exposure of the skin to UV radiation.

Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a composition for preventing induction of MMPs in human skin due to exposure of the skin to UV radiation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Wei (US 5824702).

Applicant claims composition to inhibit UV-inducement of MMPs in human skin due to exposure of the skin to UV radiation comprising an EGR-R protein tyrosine kinase inhibitor admixed in a dermatological suitable carrier.

Wei anticipates the claimed invention (see, e.g., abstract, column 2 lines 43-49) because Wei teaches a composition comprising an EGR-R protein tyrosine kinase inhibitor (i.e. genistein) admixed in a dermatologically suitable carrier whereas the claimed composition would also inherently inhibit UV-inducement of MMPs in human skin when administered to protect the skin from UV radiation. Therefore, the reference is deemed to anticipate the claimed invention.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Kelly et al. (US 6,455,032).

Kelly et al. anticipate the claimed invention (see, e.g., abstract, column 2 lines 54-62, column 7 lines 40-47 and lines 50-67), because Kelly et al. teach a composition comprising an EGR-R protein tyrosine kinase inhibitor (i.e. genistein) admixed in a dermatologically suitable carrier whereas the claimed composition would also inherently inhibit UV-inducement of MMPs in human skin when administered to protect the skin from UV radiation. Therefore, the reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wei and Kelly et al. in view of Moldenhauer et al. (US 5,985,296), Rhodes (US 4,082,679) and Fisher et al. (US 6,130,254).

Applicant claims composition to inhibit UV-inducement of MMPs in human skin due to exposure of the skin to UV radiation comprising an EGR-R protein tyrosine kinase inhibitor, a retinol, a P-450-inhibitor, a UVA blocker and UVB blocker admixed in a dermatological suitable carrier.

Both Wei and Kelly et al. teach the claimed composition of an EGR-R protein tyrosine kinase inhibitor admixed in a dermatological suitable carrier to protect the skin from UV radiation. Wei nor Kelly teach the inclusion within their composition of a retinol, a P-450 inhibitor, a UVA blocker and a UVB blocker to protect the skin from UV radiation.

Moldenhauer et al. benefically teach (see, e.g. column 1 lines 31-40) retinol as an active ingredient to protect the skin from UV radiation.

Rhodes benefically teaches (see, e.g, column 1 lines 66-68 and column 2 lines 1-7) a P-450 inhibitor (i.e. triazole) as an active ingredient to protect the skin from UV radiation.

Fisher et al. beneficially teach (see, e.g., column 3 lines 33-47) a UVA blocker and a UVB blocker as active ingredients to protect the skin from UV radiation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify both the teachings of Wei and/or Kelly et al. to include the beneficial teachings of Moldenhauer et al., Rhodes and Fisher et al for the creation of

an improved synergistic claimed composition to protect the skin from UV radiation whereas the claimed synergistic composition would also intrinsically inhibit UV-inducement of MMPs in human skin when administered.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Brumback

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